Claims:

What is claimed is:

1. A biopharmaceutical product cryopreservation system, for cryopreserving a biopharmaceutical product, comprising

a cryopreservation compartment;

a cryopreservation fluid located within the cryopreservation compartment; and

a biopharmaceutical product cryopreservation vial located within the cryopreservation compartment and surrounded by the cryopreservation fluid, and

the biopharmaceutical product cryopreservation vial comprising a body that comprises an oblong cross-section defining proximal and distal ends of the body, and at least one nucleating structure, coupled to a distal end of the body, and the body comprising a cryogenically stable material that is compatible with biopharmaceutical products.

2. The biopharmaceutical product cryopreservation system of claim 1, wherein the cryopreservation compartment comprises one or more cooling surfaces.

3. The biopharmaceutical product cryopreservation system of claim 2, wherein the one or more cooling surfaces comprise one or more internal surfaces of the cryopreservation compartment.

4. The biopharmaceutical product cryopreservation system of claim 2, wherein the one or more cooling surfaces comprise two or more cooling surfaces spaced apart from one another.

5. The biopharmaceutical product cryopreservation system of claim 4, wherein a distance between two or more cooling surfaces spaced apart from one another ranges from about 0.1 mm to about 1500 mm.

6. The biopharmaceutical product cryopreservation system of claim 1, wherein the cryopreservation fluid comprises biological cell cryoprotectants, vitrifying agents, components of biopharmaceutical drug formulations, distilled water, buffers, carbohydrates in water, salts and carbohydrates in water, PEG in water, or detergent/surfactant in water.

7. The biopharmaceutical product cryopreservation system of claim 6, wherein the biological cell cryoprotectants comprise penetrating or nonpenetrating cryoprotectants.

8. The biopharmaceutical product cryopreservation system of claim 6, wherein the vitrifying agents or components of biopharmaceutical drug formulations comprise surfactants, PEG, carbohydrates, polyols, amino acids or proteins other than the biopharmaceutical product.

9. The biopharmaceutical product cryopreservation system of claim 1, wherein the biopharmaceutical product cryopreservation system comprises more than one cryopreservation vial.

10. The biopharmaceutical product cryopreservation system of claim 1, wherein the cryopreservation vial comprises media, and the media comprises the biopharmaceutical product.

11. The biopharmaceutical product cryopreservation system of claim 10, wherein the cryopreservation fluid and the media are substantially identical in composition.

12. The biopharmaceutical product cryopreservation system of claim 10, wherein a thermal conductivity and/or a specific heat of the cryopreservation vial are substantially similar to those of the media or the cryopreservation fluid.

Patent Application

13. A method of cryopreserving biopharmaceutical products comprising

providing a cryopreservation compartment;

locating a biopharmaceutical product cryopreservation vial within the cryopreservation compartment, wherein the biopharmaceutical product cryopreservation vial comprises a body that comprises an oblong cross-section defining proximal and distal ends of the body, and at least one nucleating structure, coupled to a distal end of the body, and the body comprising a cryogenically stable material that is compatible with biopharmaceutical products.

locating a cryopreservation fluid in a space outside of the cryopreservation vial but within the cryopreservation compartment; and

removing heat from the cryopreservation compartment, thereby freezing the cryopreservation fluid.

14. The method of claim 13, wherein the cryopreservation vial comprises media, and the media comprises the biopharmaceutical product.

15. The method of claim 13, wherein the heat is removed at a rate that substantially maintains a temperature driving force within the cryopreservation compartment so as to promote a substantially constant freezing front velocity within the cryopreservation compartment.

16. The method of claim 13, wherein the heat is removed at a rate that varies so as to vary an interdendritic spacing at an edge of, or within, a solid front, wherein the solid front is located within the cryopreservation compartment.

17. The method of claim 13, wherein the cryopreservation compartment comprises one or more cooling surfaces.

18. The method of claim 17, wherein the one or more cooling surfaces comprise one or more internal surfaces of the cryopreservation compartment.

19. The method of claim 17, wherein the one or more cooling surfaces comprise two or more cooling surfaces spaced apart from one another.

20. The method of claim 19, wherein a distance between two or more cooling surfaces spaced apart from one another ranges from about 0.1 mm to about 1500 mm.

21. The method of claim 13, wherein the cryopreservation fluid comprises biological cell cryoprotectants, vitrifying agents, components of biopharmaceutical drug formulations, distilled water, buffers, carbohydrates in water, salts and carbohydrates in water, PEG in water, or detergent/surfactant in water.

22. The method of claim 21, wherein the biological cell cryoprotectants comprise penetrating or nonpenetrating cryoprotectants.

23. The method of claim 21, wherein the vitrifying agents or components of biopharmaceutical drug formulations comprise surfactants, PEG, carbohydrates, polyols, amino acids or proteins other than the biopharmaceutical product.

24. The method of claim 13, wherein the biopharmaceutical product cryopreservation system comprises more than one cryopreservation vial.

25. The method of claim 13, wherein the cryopreservation vial comprises media, and the media comprises the biopharmaceutical product.

26. The method of claim 25, wherein the cryopreservation fluid and the media are substantially identical in composition.

27. A biopharmaceutical product cryopreservation vial comprising:

a body that comprises an oblong cross-section defining proximal and distal ends of the body,

at least one nucleating structure, coupled to a distal end of the body, and

the body comprising a cryogenically stable material that is compatible with biopharmaceutical products.

28. The biopharmaceutical product cryopreservation vial of claim 27, wherein the cryopreservation vial comprises media, and the media comprises a biopharmaceutical product.

29. The biopharmaceutical product cryopreservation vial of claim 27, wherein the cryogenically stable material that is compatible with biopharmaceutical products comprises a polymer.

30. The biopharmaceutical product cryopreservation vial of claim 27, wherein the polymer comprises polytetrafluoroethylene, polystyrene, polyethylene or polypropylene.

31. The biopharmaceutical product cryopreservation vial of claim 27, wherein surface treatments have been applied to a surface of the biopharmaceutical product cryopreservation vial.

32. The biopharmaceutical product cryopreservation vial of claim 27, further comprising a vial focusing tip, coupled to the distal end of the body, wherein the vial focusing tip comprises the nucleating structure, and serves to focus heat flux from an oncoming solid front.

33. The biopharmaceutical product cryopreservation vial of claim 32, wherein the vial focusing tip comprises external heat transfer fins.

34. The biopharmaceutical product cryopreservation vial of claim 32, wherein the vial focusing tip comprises internal heat transfer fins.

35. The biopharmaceutical product cryopreservation vial of claim 27, further comprising a vial deflecting tip, coupled to the distal end of the body, wherein the vial deflecting tip comprises the nucleating structure, and serves to deflect oncoming solid front heat flux away from the cryopreservation vial.

36. The biopharmaceutical product cryopreservation vial of claim 27, wherein the nucleating structure comprises one or more points of local proximity.

37. The biopharmaceutical product cryopreservation vial of claim 27, wherein the nucleating structure comprises two or more points of local proximity.

38. The biopharmaceutical product cryopreservation vial of claim 36, wherein the one or more points of local proximity comprise wall internal sides of the cryopreservation vial that are formed into extensions located opposite to each other.

39. The biopharmaceutical product cryopreservation vial of claim 38, wherein internal surface tips of the extensions are spaced apart from about 0.001 mm to about 1 mm.

40. The biopharmaceutical product cryopreservation vial of claim 39, wherein internal surface tips of the extensions are spaced apart from about 0.04 mm to about 0.5 mm.

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